COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 21.8.2009
C(2009)6631

COMMISSION DECISION

of 21.8.2009

amending the marketing authorisation for "TARGRETIN - bexarotene", a medicinal product for human use, granted by Decision C(2001)818

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION DECISION

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amending the marketing authorisation for "TARGRETIN - bexarotene", a medicinal product for human use, granted by Decision C(2001)818

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the third subparagraph of Article 4(5) thereof,

Having regard to the notifications submitted by Eisai Limited under Article 4(1) of Regulation (EC) No 1085/2003,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Whereas:

(1) The European Medicines Agency acknowledged, between 5 February 2009 and 5 August 2009, the validity of the notification(s) for minor variations of type IA, informing the marketing authorisation holder accordingly, and has prepared a list of the notification(s). The variation(s) took effect from the date of the communication from the European Medicines Agency concerning the validation.

(2) Eisai Limited submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet,

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 159, 27.6.2003, p. 24.
3 OJ L 311, 28.11.2001, p. 67.

which has (have) not yet been included in Decision C(2001)818 of 29 March 2001.

(3) The marketing authorisation should be updated, and Decision C(2001)818 of 29 March 2001 amended accordingly.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2001)818 is amended as follows:

1) The following list of notifications for minor variations is added to the updated marketing authorisation.

Application number	Scope (EU numbers affected)
EMEA/H/C/326/IA/027	8.b.1 (IA) (EU/1/01/178/001)
EMEA/H/C/326/IA/28	1 (IA) (EU/1/01/178/001)

2) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/326/N/026	IIIB (EU/1/01/178/001)

3) Annex I is replaced by the text set out in Annex I to this Decision;

4) Annex II is replaced by the text set out in Annex II to this Decision;

5) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Eisai Limited, European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom.

Done at Brussels, 21.8.2009

For the Commission
Heinz ZOUREK
Director-General